STANDARD OPERATING PROCEDURE
Spirometry
SOP 8.6.1

Rev 5/01

PURPOSE: TO PROVIDE GUIDANCE IN THE USE OF SPIROMETRY.

Spirometry is a basic test of pulmonary function. This test measures the airflow rate and volume obtained in a patient's maximum exhalation effort. This is the most commonly performed primary pulmonary function test (PFT). It is convenient and practical to perform the spirometry test in an ambulatory setting. Spirometry is important because it can:

1. Identify the presence of small airway disease.
2. Identify pulmonary disease symptoms (restrictive, obstructive), and the degree of disability.
3. Assist in the management of patients with lung disease.
4. Provide early detection of pulmonary disease.
5. Assist in convincing patients to quit smoking.

A spirometry test can detect pulmonary disease in its early stages. Without the aid of this test, a patient would have to develop physical symptoms before the disease could be detected. A spirometry test is recommended as part of a periodic examination for all persons. In addition, several symptoms may indicate the need for performing a spirometry test in a patient. The American Thoracic Society suggests that individuals meeting any one of the following criteria should have at least one spirometry test performed annually or as indicated:

1. Pre-placement Examinations
2. History of shortness of breath upon exertion or at rest
3. History of chronic cough or sputum production
4. History of wheezing or chest tightness
5. History of frequent colds or allergic rhinitis
6. Early detection of congestive heart disease
7. Occupational exposure to inhaled dust or chemicals
8. Follow-up visits of all patients with asthma, bronchitis, and other lung diseases
9. Management of all patients on bronchodilators
10. Documentation of pulmonary disability
11. Pre-operative for all patients scheduled for thoracic and upper-abdominal surgery
12. To evaluate the effects of environmental air pollution

I. EQUIPMENT USED

The QRS Spirocard along with the MedicAir PC software is the equipment used by the DIHS for spirometry testing. This equipment, together with the disposable mouthpiece and pressure tube, is a compact and versatile microprocessor-based pulmonary function analyzer (refer to the SpiroCard Users Manual). Each disposable mouthpiece is pre-calibrated and designed for a single patient use. This unit measures the patient's expiratory and inspiratory airflow and analyzes the data. Its features include measurement of Forced Vital Capacity (FVC), Maximum Voluntary Ventilation (MVV), Slow Vital Capacity (SVC), and Pre- and Post-bronchodilators comparison. The interpretation criteria are based on suggestions of the 1994 pulmonary impairment and disability committee of the American Thoracic Society (Office Spirometry: A Practical Guide to the Selection and Use of Spirometers). The SpiroCard has the characteristics required to provide an effective diagnostic test and it meets the standards set by the American Thoracic Society Standardization of Spirometry, 1994 Update (See SpiroCard Users Manual).

II. RESPONSIBLE AUTHORITY

Spirometry should be administered under the direction of a doctor (MD, DO, or Ph.D.) trained in pulmonary function testing. The value of spirometry results can be compromised by poor patient instruction secondary to inadequate technician training (see AARC Clinical Practice Guideline, Spirometry, 1996 Update). Thus, technicians should have documented training, with continued competency assessments in spirometry administration and recognition of causes for errors encountered in the testing process and a sound understanding of physiologic effects caused by bronchodilators. They should be trained in basic life support and emergency procedures appropriate to the setting.

III. MONITORING

The following should be evaluated during the performance of spirometric measurements to ascertain the validity of the results:

A. Level of effort and cooperation by the subject.
B. Equipment function or malfunction (e.g., calibration).
C. The final report should contain a statement about test quality.
D. Spirometry results should be subject to ongoing review by a supervisor, with feedback to the technologist. Quality assurance and/or quality improvement programs should be designed to monitor technician competency, both initially and on ongoing basis.

IV. FREQUENCY

The frequency with which spirometry is repeated should depend on the clinical status of the subject and the indications for performing the test.

V. SPIROMETER SUPPLIES

A. Computer with PC Card Slot
B. MedicAir PC spirometry software
C. SpiroCard
D. Mouthpiece
E. Pressure Tube

VI. UNIT CONFIGURATION, AND SETUP: (SEE SPIROCARD USERS MANUAL)

VII. EQUIPMENT QUALITY CONTROL

The SpiroCard is built to meet or exceed the specifications incorporated in the American Thoracic Society Standardization of Spirometry, 1994 Update. The equipment utilizes the patented QRS disposable mouthpiece. Each mouthpiece is individually pre-calibrated to assure accuracy. Enter the number on the mouthpiece label. If a duplicate is encountered the software will ask for a lot number. The lot number is in the lower right hand corner and begins with "L".

The spirometer should be calibrated over their entire volume range (in 3-liter increments) quarterly using a calibrated 3-liter syringe. See Section 8.5 of the SpiroCard Users Manual for the correct procedure.

VIII. PATIENT'S PERSONAL INFORMATION

Go into Patient Files on the computer screen and follow the instructions (See Spirocard Users Manual section 7.1).

IX. SPIROMETRY TEST PROCEDURE

A. **Establish rapport**
To obtain valid test results from a spirometric test, the patient must be put at ease. This is accomplished by initially greeting the patient and assuring him that the test is simple and non-painful, with the purpose of measuring how much air can be exhaled after a maximal inhalation and how fast it can be blown out.

B. **Ask prescreening questions** and check blood pressure (see appendix #1).

C. **Ask respiratory symptoms** questionnaire if indicated (see appendix #2).

D. **Give test instructions**
The patient's cooperation will depend on a complete test explanation. The better the subject understands the maneuver, the better the results will be. Every patient should be in a standing or sitting position (be consistent) for the test. Place a chair behind the patient, if standing, to allow for him to sit down should dizziness be experienced. Loosen all tight clothes.

Give the instruction in two parts:

Comment: Should these be numbered 1 and 2 since you are talking about 2 parts? Joan

E. **Describe the maneuver**

Stand (or sit) straight with chin up. Take the deepest breath you can, then place the mouthpiece in your mouth, on top of your tongue (to ensure the tongue does not occlude the mouthpiece) and tightly seal your lips around the tube. Stop here and show how the mouthpiece is placed over the tongue. Continue by saying, "I want you to **'Blast'** the air out as hard and fast as you can, and keep blowing hard until you have no more air left!"

F. **Demonstrate the maneuver**

"Now watch how I do it." Take a different mouthpiece and carefully show each step in the procedure, with your maximal effort (your demonstration is setting the example, so make it real). At the beginning of the exhalation maneuver, do not bend forward, stand upright with your chin elevated.

G. **Administer the test**

Your task, as the technician, is to ensure that the spirometry test you obtain reflects the true picture of lung performance. The confidence that is placed in the best trial is enhanced when the second best trial reproduces the best trial. Due to the "learning curve," it usually requires several attempts to achieve the optimal spirogram. First obtain three maneuvers. If satisfactory data has not been obtained after three attempts, rest the patient and then do up to five more maneuvers, for a total of eight.

1. Before commencing the first maneuver, the patient should have the mouthpiece firmly attached to the pressure tube and their hands firmly around it.
2. A maximal inhalation is taken from room air before placing the mouthpiece in the mouth.

H. **See the SpiroCard Users Manual section 7.1.**

X. SPIROMETRY RECORD

A spirometry record should be filed at each clinic. A spirometry record consists of the following documents:

1. Questionnaires with employee signature (medical record).
2. Dated calibration records, problems encountered, corrective action required, and system hardware and/or software changes.
3. Equipment maintenance records.
4. Spirometry tracing and results. Hardcopy for the medical record and results saved on the computer.

XI. TESTING, ENVIRONMENTAL CONTROLS

Physiologic measurements such as spirometry, which require subject concentration and cooperation, vary depending on the environment at the time of the measurement. Temperature, humidity, noise level, light intensity, visual distractions, and relative privacy are a few of the many factors that have been shown to directly influence the results of measurement. Do not test when ambient temperatures are less than 17C or above 40C, since the ability of the BTPS (body temperature and pressure, saturated) factor to correct volume may be compromised.

XII. INFECTION CONTROL

The Spirometer uses a disposable mouthpiece that is designed for single patient use. The mouthpiece is never to be used for more than one patient. The design is intended to reduce the risk of contamination. There are two sources of cross contamination from spirometry, direct and indirect. Direct contact, from handling mouthpieces and tubing, can lead to upper respiratory, enteric, and blood borne infections. Hepatitis and HIV are possible from open sores on the mucosa, bleeding gums or hemoptysis. Indirect contact comes from aerosol droplets and can lead to tuberculosis, viral, opportunistic, and nosocomial infections. Universal precautions should be applied in all instances in which there is the potential for exposure to blood and body fluids. The appropriate use of barriers (i.e., gloves) and handwashing are recommended. To prevent infection:

1. Use a new disposable mouthpiece for subjects and have them discard the wrapper.
2. Connect it to the pressure tube and to the SpiroCard.
3. Use open circuit testing technique: Instruct the patient not to inhale from the spirometer during testing.
4. Have subject remove the mouthpiece and dispose into a hazardous waste receptacle after completion of the test.
5. Have several spirometers pressure tubes and mouthpieces at the station.
6. Wash hands between subjects, and use latex gloves where appropriate.

XIII. CLEANING OF THE SPIROCARD

If the SpiroCard becomes dirty, clean the surfaces with a damp cloth using water only. Dry thoroughly. Avoid cleaning around Luer.

XIV. TROUBLESHOOTING

See the SpiroCard Users Manual.

XV. SERVICE AND WARRANTY

The SpiroCard is guaranteed to be free from defects in material and workmanship for a period of three years from the date of purchase.

APPENDIX #1

Pre-screening Questions

To be completed by a medical provider prior to testing

Name: _____ **Site:**_____
A#:_____ **Date:**_____

Height:_____ **inches** **Weight:**_____
If measurement falls exactly on the half inch, or half pound, odd numbers round down and even numbers round up respectively.

BP (mmHg): ____/____ ____/____ ____/____
Determine if there is any condition which may require postponement of the test or may cause the test to be invalid.

____Yes____No **In the last 6 weeks have you had major surgery or been hospitalized for a heart attack?**
(If yes: do not test at this time. Reschedule for test in 6 weeks).

____Yes____No **Are you under a physicians care for high blood pressure?**
(If blood pressure exceeds action level, obtain physicians clearance. Do not perform the test if diastolic pressure is 118 mmHg or greater or systolic pressure is 200 mmHg or greater).

____Yes____No **Within the last hour have you smoked tobacco?**
(If yes: wait one hour before testing).

____Yes____No **Within the last hour have you eaten a full meal?**
(If yes: wait one hour before testing).

____Yes____No **Have you had a respiratory infection (such as flu, pneumonia, bronchitis, or a chest cold) in the last 3 weeks?**
(If yes, and symptoms still present: reschedule test in 6 weeks).

____Yes____No **Have you used an inhaled bronchodilators (Primatine Mist, Ventolin, etc.) in the last 6 hours?**

____Yes____No **Have you had more than 2 cups of caffeinated coffee, tea or cola (total) in the last 6 hours?**
(If yes: wait one hour before testing. Continue with spirometry testing now and schedule to retest in 6 weeks).

____Yes____No **Are you wearing any tight or restrictive clothing?**

____Yes____No **Are you wearing dentures?**

Provider initials:_____ **Date:**_____

APPENDIX #2

RESPIRATORY SYMPTOM QUESTIONNAIRE

Name: _____ **Site:**_____
A#:_____ **Date:**_____

COUGH AND PHLEGM

YES NO 1. Do you usually cough in the morning, day or night?
If yes:
YES NO 1a. Do you cough on most days within a 3-month period of the Year?
If yes:
_____ 1b. For how many years have you had this cough?

YES NO 2. Do you usually bring up phlegm from your chest in the morning, day or night?
If yes:
YES NO 2a. Do you bring up phlegm on most days within a 3-month period of the year?
If yes:
_____ 2b. For how many years have you brought up phlegm?

BREATHLESSNESS

YES NO 3. Does your chest ever feel tight or your breathing difficult?

YES NO 4. Do you have shortness of breath when hurrying on level ground or walking on a slight hill?
If yes:
YES NO 4a. Do you get short of breath walking on level ground with people your own age?
If yes:
YES NO 4b. Do you have to stop for breath while walking on level ground at your own pace?
If yes:
YES NO 4c. Do you become short of breath while washing or dressing?

WHEEZING

YES NO 5. Does your breath ever sound wheezy or whistling?
If yes:
_____ 5a. For how many years has your breathing sounded wheezy or whistling?

YES NO 6. Do you have asthma? (Physician confirmed)
If yes:
_____ 6a. How old were you when asthma started?
If yes:

YES NO 6b. Do you take any medications for asthma?

HISTORY

YES NO 7. Have you ever had hay fever?
If yes:

YES NO 7a. Did you have hay fever this year?

YES NO 8. Do you have allergies other than drug allergies?
If yes:

YES NO 8a. Have you ever been skin tested for allergies?
If yes:

YES NO 8b. Were your allergy skin test results positive?

YES NO 9. Have you ever had pneumonia?

YES NO 10. Have you ever had tuberculosis?

YES NO 11. Have you ever had heart disease?

YES NO 12. Have you ever had any other types of chest disease?

YES NO 13. Has a doctor ever told you that there was something wrong with your chest x-ray?

SMOKING HISTORY

C E N 14. Are you a current (C) Ex (E), or Never (N) cigarette smoker?
If an Ex-Smoker:
_____ 14a. How old were you when you began smoking?

YES NO 14b. Did you quit smoking within the past 12 months?
_____ 14c. How old were you when you quit smoking?

If a current smoker:

_____ 14d. How old were you when you began smoking?

_____ 14e. On average, how many packs do you smoke daily?

OCCUPATIONAL HISTORY

YES NO 17. Have you ever worked, or do you now work around dust, fumes, smoke, gasses or chemicals?

YES NO 17a. Have you ever worked, or do you now work in a foundry, mine or quarry?

If yes:

_____ 17b. How many years have you worked in a foundry, mine or quarry?

YES NO 17c. Have you ever worked, or do you now work in sandblasting?

If yes:

_____ 17d. How many years have you worked in sandblasting?

YES NO 17e. Have you ever worked, or do you now work with asbestos?

If yes:

_____ 17f. How many years have you worked with asbestos?

YES NO 17g. Have you ever worked, or do you now work in a textile mill containing cotton dust?

If yes:

_____ 17h. How many years have you worked around cotton dust?

YES NO 17i. Have you ever worked, or do you now work with irritant chemicals?

If yes:

_____ 17j. How many years have you worked with irritant chemicals?

Provider signature _____ Date_____--